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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,694	10/02/2003	Nader Najafi	IB-8	9770

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-31,33-44,46-58,60-63 and 65-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31* is/are allowed.

6)☒ Claim(s) *1-14,17-30,33-44,46-58,60-63 and 65-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Response to Amendment

The amendment filed 2/2/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New figure 6 shows an external reader 104, 202 being the same as the non-implantable readout unit, wherein reference numeral 104, 202 were previously used to refer to the non-implantable readout unit, and being provided in addition to an external power unit. Figure 6 also shows each of the pacing/ICD unit 106, the reader unit/non-implantable readout unit 104, 202, and the separate external power unit 107 as providing power to the implantable sensing unit 101, 201. Neither of these details have been previously addressed in the instant specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawing Objections

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 106, 107 in figure 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or

amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet or "New Sheet pursuant to 37 CFR 1.121(d) If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The

objection to the drawings will not be held in abeyance.

Objections to the Specification

The disclosure is objected to because of the following informalities:

The specification fails to describe the system including the non-implantable readout device, as claimed, in combination with any of the pacing/ICD unit, external unit, or external reader. The description on p. 11 of the specification merely describes an embodiment comprising the pacing/ICD unit and either an external unit solely for transmitting power *or* an external reader for interrogating and/or powering the sensor.

The brief description of drawings lacks a description of figure 6.

Appropriate correction is required.

Claim Objections

Claims 1, 2, 43, 47, and 55 are objected to because of the following informalities:

On line 20 of claim 1, "a patient pacemaker" should be replaced with "the pacing/ICD unit".

On line 14 of claim 2, "a patient pacemaker" should be replaced with "the pacing/ICD unit".

On line 2 of claim 43, "the portion" should be replaced with "a portion".

On line 2 of claim 47, "trabeculated" should be replaced with "trabeculate" or "trabecular".

On line 2 of claim 55, "trabeculated" should be replaced with "trabeculate" or "trabecular". Appropriate correction is required.

Rejections under 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 17-30, 35-44,46-58,60-63, and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites both a "non-implantable readout device ... comprising at least one inductor coil having telemetric means for at

least one of electromagnetic telecommunication and electromagnetic wireless powering of said sensing device through said at least one inductor coil of said sensing device" and at least one of "an external unit solely for transmitting power to said at least one sensing device" and "an external reader . . which . . retransmits data to the pacing/ICD unit". Claim 2 recites the same limitations except that the non-implantable readout device allows both telecommunication and wireless powering. Page 11 describes an embodiment in which the system is part of a closed-loop pacing/ICD tuning system. This embodiment fails to address the combination of both the non-implantable readout device, as claimed, and either or both of the external unit and reader. The specification fails to clearly explain how to make or use a system that includes non-implantable readout device, as claimed, in combination with any of the pacing/ICD unit, external unit, or external reader, such that one of ordinary skill in the art would be unable to make and/or use the claimed system without undue experimentation, particularly in the case where the non-implantable readout device accomplishes both electromagnetic telecommunication and electromagnetic wireless powering of the sensing device. It is unclear why the system would need both the non-implantable readout device and either the external unit or external reader and how all the nonimplantable readout device and external unit or reader would be used together in the system with respect to each other, the sensor, and the pacing/ICD unit. It is noted that newly added figure 6 addresses some aspect of the combination of external/non-implantable units. However, the figure cannot be relied upon because it contains new matter, as described above.

Rejections under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 6, 9, 11, 12, 17, 19, 21, 23, 25, 27, 29, 37, 38, 41-44, 46, 47, 60, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,409,674 to Brockway et al. in view of US Patent No. 5,704,352 to Tremblay et al. and US Patent No. 6,636,769 to Govari et al. Brockway teaches a system for diagnosis of congestive heart failure within a patient. The system comprises at least one sensing device 305 adapted to be implanted in a cavity of the patient's cardiovascular system. The sensing device comprises an anchoring mechanism, and at least one sensor (see entire document, especially figs. 1, 3A-3D; col. 8, line 10-col. 9, line 42 of Brockway). A non-implantable readout device is not adapted to be implanted in the patient and is configured to recharge battery 335 that powers the sensing device 305 (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway). The system is part of a closed-loop pacing/ICD tuning mechanism comprising a pacing/ICD unit. Data from the sensing device is sent to the pacing/ICD unit for tailoring of the pacing/ICD function (see entire document, especially figs. 4 &5; col. 11, lines 14-62 of Brockway). Brockway is silent as to the communication scheme that results in the sensor sending data to the pacing/ICD unit, and as to the how the external readout device recharges the battery.

However, Tremblay teaches a communication scheme, wherein the sensor sends sensed data to a secondary unit upon interrogation of the sensor by the secondary unit (see entire document, especially col. 4,lines 43-51 of Tremblay). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the communication scheme of the secondary unit (pacing/ICD unit)interrogating the sensor in order to elicit transmission of data from the sensor to the secondary unit in the system of Brockway, since Brockway teaches the sensor sending data to the pacing/ICD unit, and Tremblay discloses an appropriate method of doing so. Brockway, as modified, is still silent as to how the external readout device recharges the battery.

However, Govari teaches an external readout device that recharges a sensing device, wherein each of the readout device and sensing device comprise an inductive coil having telemetric means for electromagnetic wireless powering of the sensing device (see entire document, especially figs. 8, 9; col. 8, line 48-col. 9, line 39 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the recharging means of Govari as that of Brockway, as modified, since Brockway teaches using an external device to recharge the sensing device battery, and Govari discloses an appropriate means for doing so.

As to the language "for monitoring . . . for diagnosis of congestive heart failure" and "implantable so that a portion of said anchoring mechanism passes through a septum of the heart and, to minimize the risk of thrombogenicity, a larger portion of said implantable sensing device is located in the right side of the heart and a smaller portion

of said implantable sensing device is located in the left side of the heart", the applicants should note that this is merely "intended use" language describing the intended positioning of the sensing device upon implantation. This language cannot be relied upon to define over the prior art, since Brockway, as modified, teaches all of the claimed structural elements and their recited relationships. The device of Brockway, as modified, is certainly capable of being used for diagnosis of congestive heart failure (see entire document, especially col. 1, lines 38-60 of Brockway), or of being implanted in such a way as described in claim 1.

Regarding claims 5 and 6, the sensing device includes a battery, and the battery is rechargeable using wireless means (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claims 9 and 23, the at least one physiological parameter includes pressure (see entire document, especially col. 7, lines 12-27 of Brockway).

Regarding claims 11 and 25, the applicants should note that the type of pressure sensed, as listed in claim 11, are merely a result of the location of the implantation of the sensing device. Therefore, the pressure types are merely "intended use" language, being reliant upon the intended use, since the intended location of the implantation is intended use. This language cannot be relied upon to define over the prior art, since the prior art teaches all of the claimed structural limitations and their recited relationships. The device of Brockway, as modified, is certainly capable of being implanted in such a location so as to monitor or sense the listed pressures. Additionally, the sensing device may be located in any one of the chambers of the heart such that

right or left atrial or ventricular pressure may be sensed (see entire document, especially col. 7, lines 14-37 of Brockway).

Regarding claim 12, the system calculates the change of pressure over time (dp/dt) (see entire document, especially col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claim 17, a resonant scheme is used to couple the sensing device to the readout device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway; figs. 8, 9 and col. 8, line 49-col. 9, line 39 of Govari).

Regarding claim 19, a passive scheme is used to couple the sensing device to the readout device, wherein the scheme is passive in that the sensing device may lay passive until the battery is charged or recharged by the non-implantable readout device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway; figs. 8, 9 and col. 8, line 49-col. 9, line 39 of Govari).

Regarding claim 21, an active scheme is used to couple the sensing device to the readout device, in that the non-implantable readout device must actively be brought into the vicinity of the sensing device to enable wireless powering of the sensing device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway; figs. 8, 9 and col. 8, line 49-col. 9, line 39 of Govari).

Regarding claim 27, the applicant should note that the intended use of the invention cannot be relied upon to define over the prior art since the prior art teaches all of the claimed structural elements and their recited relationships. The system of

Brockway may certainly be used for disease management or treatment, for example (see entire document, especially col. 14, lines 37-40 of Brockway).

Regarding claim 29, the readout device is adapted for use in at least battery operation capability and monitoring of patients (see entire document, especially col. 8, line 48-col. 9, line 39 of Govari).

Regarding claims 37 and 38, the sensing device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (see entire document, especially col. 11, line 65-col. 13, line 54 of Brockway)

Regarding claims 41-44, an anchoring mechanism is chosen from at least screws, tines, and stents (See entire document, especially fig. S3A-D; col. 8, line 26-52 of Brockway). With further regard to claim42, the anchoring mechanism comprises means 312D for opening on at least one side of the septal wall and adapted for clamping the device to the septal wall (see entire document, especially fig. 3C; col. 8, lines 38-57 of Brockway). With further regard to claims 43 and 44, a portion of the anchoring mechanism is adapted to pass through the atrial septum of the heart, and the anchoring mechanism comprises two umbrella shaped anchors 312D adapted to be disposed on opposite sides of the septum. Applicants should further note that language regarding the location of the sensing device or anchoring mechanism with respect to the heart or part thereof, is merely considered "intended use" language, wherein such language has been addressed above.

Regarding claim 46, the anchoring mechanism is a helical screw 312A (see entire document, especially fig. 3A of Brockway).

Regarding claim 47, the anchoring mechanism is a tine 312D, wherein the tine is capable or adapted to catch on a trabecular area of the heart (see entire document, especially fig. 3D, 7; col. 8, lines 45-52; col. 13, lines 43-47 of Brockway).

Regarding claim 57, the sensing device is augmented with at least a pacing device, voltage source or current source (see entire document, especially figs. 4 & 5, col. 9, line 64-col. 10, line 14of Brockway; figs. 8, 9; col. 8, line 48-col. 9, line 39 of Govari).

Regarding claim 60, the sensing device is directly interrogated by the pacing/ICD unit (see rejection set forth above).

Regarding claim 69, at least a portion of the implantable sensing device is coated with at least one layer of coating material (see entire document, especially col. 8, lines 34-36 of Brockway).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Tremblay and Govari, as applied to claims above, and further in view of US Patent No. 6,120,457 to Coombes et al. Brockway, as modified, describes the pressure sensor as being, in one embodiment, resistive, rather than capacitive (see entire document, especially col. 9, lines 30-42 of Brockway). However, Coombes teaches that an implantable pressure sensor may be capacitive or resistive (see entire document, especially col. 1, lines 21-30 of Coombes). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a capacitive sensor in place

of the resistive sensor of Brockway, as modified, since Coombes teaches capacitive and resistive pressure sensors to be functionally equivalent.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Tremblay and Govari, as applied to claims above. Brockway, as modified, teaches the anchoring mechanism may be made form a memory metal (see entire document, especially col. 8, lines 47-49 of Brockway), but is silent as to the specific metal used. However, Govari teaches an implantable sensor having an anchoring mechanism made from a memory metal such as nitinol (see entire document, especially col. 6, lines 43-45 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use nitinol as the material for the anchoring mechanism of Brockway, as modified, since Brockway, as modified, teaches using an anchoring mechanism, and Govari teaches nitinol as an appropriate memory metal for such an anchoring mechanism.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Tremblay and Govari, as applied to claims above, and further in view of US Patent No. 5,067,491 to Taylor, II et al. Brockway, as modified, lacks a coating, as recited in claim 70. However, Taylor, II teaches an implantable pressure senor, wherein at least the sensing portion of the sensor is coated in a thin layer of parylene (see entire document, especially col. 2, line 27-col. 3 of Taylor, II). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to

use the coating of parylene of Taylor, II on the sensing portion of the sensing device of Brockway, as modified, in order to extend the life of the sensor by protecting the implant form damage by body fluids (see entire document, especially col. 1, line 47-22; col. 2, line 57-col. 3, line 7 of Taylor, II).

Response to Arguments

Applicants' arguments with respect to the claims have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

No prior art has been applied to claims 2, 4, 7, 8, 10, 13, 14, 18, 20, 22, 24, 26, 28, 30, 33-36, 39, 40, 49-56, 58, 61-63, 65-68, and 71. In light of the rejection under 35 U.S.C. 112, 1st paragraph, the claims are not allowable. The prior art will be revisited upon resolution of the rejection under 35 U.S.C. 112, 1st paragraph.

Claim 31 is allowed. The allowability of this claim was addressed in the previous Office actions, filed 11/2/05 and 8/14/06.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is 571-272-4729. The examiner can normally be reached on Mon-Fri, 10 am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/pcm